



Cardiology News

THE LEADER
IN NEWS
AND
MEETING
COVERAGE

VOL. 7, No. 1

The Leading Independent Newspaper for the Cardiologist

JANUARY 1, 2009



DAVID ROSE/MAYO CLINIC ARIZONA

Dr. Bentley J. Bobrow demonstrates insertion of an intravascular catheter used for cooling a resuscitated cardiac arrest patient.

Cooling for Cardiac Arrest Catches On

BY MITCHEL L. ZOLER
Philadelphia Bureau

It has taken about 7 years, but treating comatose survivors of cardiac arrest by cooling them down is finally hot.

In February 2002, reports from two independent, controlled studies published in the same journal issue showed dramatically improved neurologic and survival outcomes in patients resuscitated after cardiac arrest when their body temperatures were dropped to 32° C-34° C for 12-24 hours (N. Engl. J. Med. 2002;346:549-56; 557-63). But despite an editorial that enthusiastically recommended immediate adoption of the treatment into the care of cardiac arrest survivors (N. Engl. J. Med. 2002;346:612-3), and further endorsement by the Advanced Life Support Task Force of the International Liaison Committee on Resuscitation in April 2003 (Resuscitation 2003;57:231-5), the treatment mostly languished for several years.

As recently as 2006, a survey of U.S. emergency medicine physicians, critical care physicians, and cardiologists found that 74% of respondents had never used therapeutic hypothermia (TH) in cardiac arrest patients (Crit. Care Med. 2006;34:1935-40).

Experts cite many reasons for the slow uptake, despite overwhelming evidence of the efficacy and safety as well as the relative simplicity and low cost of TH. Perhaps the most frequently cited explanation is the "legacy of nihilism" for treating CPR survivors, after decades of seeing most of these patients go on to a poor quality of life, said Dr. Clifton W. Callaway, an emergency medicine physician at the University of Pittsburgh. He also noted the small number of cardiac arrest survivors that any single physician usually sees, making him or her unfamiliar with these patients, and the relatively low level of commercialization of TH. The absence of a billing code and re-

See **Cardiac Arrest** page 8

INSIDE

Risky Business

Will the new
Reynolds Risk Score
replace Framingham?
Not so fast, critics say.

PAGE 4



Resistant Atrial Fibrillation

Catheter ablation
outperforms drugs.

PAGE 6

Survey Says

Patients' perceptions
of elective PCI
are way off.

PAGE 12



Folic Acid

Periconceptual supplements
reduced congenital heart
malformations.

PAGE 17

Ischemic Events Down, Bleeds Up With Rivaroxaban

Novel factor Xa inhibitor on to phase III.

BY BRUCE JANCIN
Denver Bureau

NEW ORLEANS — Now that the novel factor Xa inhibitor rivaroxaban has shown a trend toward reducing recurrent ischemic events in nearly 3,500 patients with acute coronary syndrome in the phase II ATLAS ACS-TIMI 46 trial, a pivotal phase III study is underway.

That trial involving up to 16,000 patients with recently diagnosed ACS, was set to start recruiting by the end of last year and should be completed in 2011, Dr. C. Michael Gibson announced while presenting the ATLAS ACS-TIMI 46 results at

the annual scientific sessions of the American Heart Association.

ATLAS ACS (Anti-Xa Therapy to Lower cardiovascular events in addition to Aspirin with/without thienopyridine therapy in Subjects with Acute Coronary Syndrome) showed improved clinical outcomes when rivaroxaban was added to background therapy with aspirin with or without clopidogrel, but at the cost of a dose-dependent increase in bleeding, reported Dr. Gibson, chief of clinical research in the cardiovascular division at Beth Israel Deaconess Medical Center, Boston.

This was a dose-ranging
See **Rivaroxaban** page 7

Imagify Neither Safe Nor Effective, FDA Panel Says

BY ALICIA AULT
Associate Editor, Practice Trends

SILVER SPRING, MD. — The Food and Drug Administration's Cardiovascular and Renal Drugs Advisory Committee voted 16-1 with 1 abstention that the risks of Imagify, an echocardiography ultrasound imaging agent, outweigh its benefits.

The committee members said that Imagify's manufacturer, Acusphere Inc., had not proven efficacy with its two pivotal trials, and that there were many questions remaining about short-term and long-term safety.

"There is insufficient evidence to prove efficacy," said the committee's acting chairman, Dr. Robert Harrington, director of the Duke Clinical Research Institute, Durham, N.C.

Acusphere sought approval for Imagify—composed of biocompatible, biodegradable perflubutane polymer microspheres—for use in patients with stable chest pain to assess myocardial perfusion and all motion. But committee members expressed concern that because of its relative ease of use when compared with single-

See **Imagify** page 5



DR. SIDNEY GOLDSTEIN

Gets to the Heart of the Matter.

See page 2

CARDIOLOGY NEWS
5635 Fishers Lane, Suite 6000
Rockville, MD 20852

CHANGE SERVICE REQUESTED

Presorted Standard
U.S. Postage
PAID
Permit No. 384
Lebanon Jct. KY

Hypothermia Blunts Brain Injury

Cardiac Arrest from page 1

imbursement for TH is another factor, said Dr. Bentley J. Bobrow, an emergency medicine physician at the Mayo Clinic in Phoenix. Another issue is that a diverse array of physicians, nurses, and technicians in several different specialties all need to be on board in using TH as a cardiac arrest patient is transitioned from ambulance to emergency department to coronary care unit, said Dr. Robert W. Neumar, an emergency medicine physician and associate director of the center for resuscitative science at the University of Pennsylvania, Philadelphia.

But slowly, the concept of TH gained currency and began being used by the many health care constituencies involved: emergency medical services (EMS) personnel, emergency physicians, cardiologists, neurologists, nurses, and hospital administrators. At the end of 2008, it looked like TH finally became the standard of care. "There has been a major shift in the use of TH. We've seen a substantial increase in interest," so that at the start of 2009 there is generally at least one large center routinely using TH for cardiac arrest patients in virtually every major U.S. metropolitan area, said cardiologist Mary Ann Peberdy, professor of medicine and emergency medicine at Virginia Commonwealth University in Richmond.

"The idea is to treat cardiac arrest as a potential brain injury, not just a heart injury. It's a change so that it's not CPR, it's CCR: cardiocerebral resuscitation," said Dr. Stephan A. Mayer, chief of the neurologic ICU at Columbia-Presbyterian Hospital, New York. "Cooling for cardiac arrest has been a grassroots, bottom up movement that has bubbled up where there have been local champions," and now "it's absolutely at a tipping point," Dr. Mayer said in an interview.

Although no group or registry keeps official tabs on how widely TH is used in America or elsewhere, here are a few examples of its spread:

► In December 2007, Dr. Bobrow launched a program to designate Arizona hospitals as cardiac arrest centers that required participating centers to use TH as well as other evidence-based

facets of resuscitation, report their outcomes, and have percutaneous coronary intervention available around the clock. This is the first statewide program aimed at boosting use of TH, said Dr. Bobrow, who is also medical director for the Bureau of Emergency Medical Services of the Arizona Department of Health Services, in an interview. By the end of 2008, Dr. Bobrow had enlisted 20 of the approximately 70 hospitals in Arizona into the program, and he hopes to involve another 20 centers in 2009. Before the program began, TH was available at only one Arizona hospital. The program also has EMS crews take patients to a participating cardiac arrest center while bypassing undesignated hospitals. TH use increased from 2% of cardiac arrest patients before the program began to 34%, while survival to hospital discharge rose from 13% before to 22% with the program in place. (See p. 9 for more on cardiac arrest centers.)

► Virginia Commonwealth University in Richmond was an early adopter of TH for resuscitated cardiac arrest patients, starting in late 2002, said Dr. Peberdy. But in February 2008, the program intensified. Working with the Richmond Ambulance Authority, EMS technicians began to infuse chilled saline into appropriate patients while in the ambulance to start TH as soon as possible. With cooling already begun, ambulance drivers began to take patients only to local centers with a protocol to continue TH once patients arrived, and at the time Virginia Commonwealth was the only such hospital in Richmond. Ambulance crews also improved their resuscitation methods with an automated chest-compression device designed to boost blood flow, compared with manual chest compression. February 2008 also introduced a more intensive, in-hospital program at Virginia Commonwealth: Advanced Resuscitation Cooling Therapeutics and Intensive Care (ARCTIC), modeled on a trauma-team approach. It involves a specialized team of providers trained to both continue TH and also provide state-of-the-art resuscitation

care. TH is continued in the hospital using an intravascular catheter that's threaded through the femoral vein and into the inferior vena cava. The catheter balloon contains a continuous flow of cold fluid that directly cools the patient's blood, so the target temperature of 33° C is reached within 1 hour, said Dr. Peberdy. From February through mid-December 2008, 54 resuscitated cardiac arrest patients were treated this way, with 40%-45% surviving with good neurologic outcomes, compared with a historic rate without TH of about 15%, she reported in an interview. Dr. Peberdy, who is director of ARCTIC, credits this program and the EMS diversion policy



Therapeutic hypothermia is easy to start in the field. 'There is no valid reason not to adopt this practice.'

DR. PHILIPPIDES

with forcing the hand of at least one other Richmond hospital that introduced TH following the launch of Virginia Commonwealth's program in early 2008. ► TH began to be used comprehensively at Columbia-Presbyterian in New York in mid-2007, taking hold under the leadership of Dr. Mayer. By late 2007, he and other TH advocates in New York City organized a day-long hypothermia session that led to a year-long effort to make TH available to cardiac arrest patients around the city. The initiative got a boost when it was embraced by the medical directors of the city's EMS program and the fire department. The result is that starting this year, cardiac arrest patients who are picked up by ambulances inside the city and meet the requisite clinical parameters will be taken to the closest hospital that can provide TH as long as it can be reached within 20 minutes. The program also plans to start providing prehospital cooling in the ambulance during 2009.

► Boston Medical Center began using TH in 2004, and the other large medical centers in the Boston have also begun its routine use. The program ratcheted up in mid-2008, when the Boston EMS pro-

gram began administering TH to eligible patients while they were in the ambulance, said Dr. George Philippides, director of the coronary care unit at Boston Medical Center. TH "is relatively easy to start in the field, using cold intravenous saline and ice packs. There is no valid reason not to adopt this practice," Dr. Philippides said.

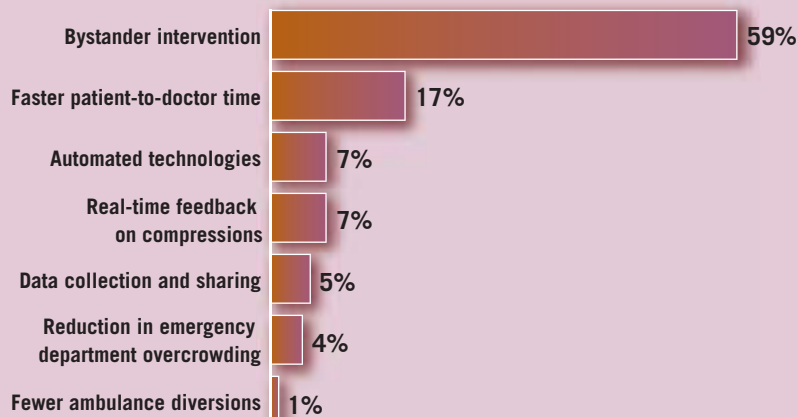
► A TH program for cardiac arrest began at the Ochsner Clinic in New Orleans in May 2007. As of late 2008, it was not clear whether TH was routinely used at other hospitals in New Orleans, said Dr. Christopher White, chairman of the department of cardiovascular diseases at Ochsner. He hopes that in 2009 a program may begin with the city's EMS to preferentially transport cardiac arrest patients to hospitals in the city that can deliver TH, a step that he predicted will likely not be controversial because "it is absolutely the right thing to do, and because we are talking about a small number of patients so hospital volume is not threatened," Dr. White said.

► A standard protocol to use TH for cardiac arrest survivors began in 2003 at the University of Pittsburgh, and in 2008 the center treated more than 100 patients this way. Other hospitals in Pittsburgh have varying levels of TH use, said Dr. Callaway from the University of Pittsburgh. "We are now discussing whether it makes sense for EMS" to only take these patients to cardiac arrest centers, just as trauma patients are only taken to specializing centers, he said in an interview.

Broader use of TH has the potential to have a substantial clinical impact, according to a 2008 analysis by researchers at the University of Michigan, Ann Arbor. They assumed that EMS crews annually treated about 70 patients for out-of-hospital cardiac arrest for every 100,000 Americans, or roughly 200,000 patients a year. Assuming that about 20% of these patients have return of spontaneous circulation, and about a third of the resuscitated patients are eligible for TH, and that six such patients need to be treated to have one improved outcome, then more than 2,000 additional Americans a year stand to survive with a good neurologic outcome if TH is routinely used for all eligible cardiac arrest patients (Resuscitation 2008;77:189-94). ■

DATA WATCH

Best Strategies to Improve Resuscitation Survival Rates



Note: Based on responses from 1,056 emergency physicians.

Source: American College of Emergency Physicians' State of Resuscitation survey

Cardiovascular Hospitalizations Declined by 17% During 2000-2005

NEW ORLEANS — The total number of hospitalizations for cardiovascular events and procedures in the United States declined by 17% during the first 6 years of this decade, according to data from the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample.

Hospitalizations for coronary heart disease fell by an age- and sex-adjusted 24% from 2000 to 2005, while heart failure admissions remained essentially constant, Craig S. Roberts, Pharm.D., reported at the annual scientific sessions of the American Heart Association.

The rate of elective coronary artery bypass graft (CABG) surgery plummet-

ed by 46%. The total number of CABG procedures decreased by 40% from more than 385,500 performed in 2000. In contrast, primary angioplasties increased by over 13%, from 2.2 per 1,000 persons in 2000 to 2.5 in 2005, while the elective angioplasty rate remained flat, according to Dr. Roberts of Pfizer Inc. in New York.

The total cardiovascular hospitalization rate was 13.8 per 1,000 in 2000, dropping to 11.5 in 2005. Coronary heart disease hospitalizations declined from 3.3 to 2.5 per 1,000 during 2000-2005. The heart failure hospitalization rate was 3.8 per 1,000 in 2000 and 3.7 in 2005.

—Bruce Jancin